

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
2. Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. There appears to be no definition of the phrase "therapeutically active amount" and only selected examples of agents and examples of amounts of physiological agent for each of the single phase means for fluid cleansing and the dual-phase means. Thus the true scope of the phrase "physiologically active components in therapeutically active amounts to promote wound healing" is unknown, rendering claim 2 indefinite.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.
4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
 1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.

Art Unit: 3761

3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
5. Claims 1-3, 6, 8, 12, 14, 15, 17 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swanbeck (WO 84/01904 A1) in view of Lockwood (U.S. Patent No. 6,685,681).

With respect to **claims 1,14,15**: The examiner is invoking 35 U.S.C. 112, sixth paragraph in the interpretation of claim 1, specifically with regard to the recited "means for fluid cleansing" and "means for supplying physiologically active agents to the wound." Swanbeck discloses an apparatus for aspirating, irrigating and cleansing wounds, comprising: characterized in that it comprises a fluid flow path, comprising the following: a suction cup 10 for placing over a wound and at least one inlet lumen for connection to a fluid supply tube 12, which passes under the wound-facing face of cup 10 and in communication with at least a fluid reservoir 15, and at least one outlet lumen 11, which passes under the wound-facing face of cup 10, wherein a relatively fluid-tight seal or closure is formed over the wound at the point at which each inlet pipe lumen and each outlet lumen passes through and/or under the wound- facing face (Page 2, ¶¶4 - Page 3 ¶¶3); a means for fluid cleansing in the form of a treatment solution in bottle 15 in communication at least with the outlet lumen via supply tube 12 (Fig. 1); a fluid recirculation lumen 11 for directing cleansed fluid from the means for fluid cleansing back into the inlet lumen; a device, peristaltic pump 13, for moving fluid through at least the wound dressing and the means for fluid cleansing; means in the form of a solution in bottle 15 and bottle 15 for supplying physiologically active agents to the wound (Page 4, ¶¶ 1, 2)

Swanbeck discloses an external bandage for applying pressure to the wound, but does not explicitly disclose a conformable wound dressing, comprising a backing layer which is

Art Unit: 3761

capable of forming a relatively fluid-tight seal or closure over a wound and a wound-facing face, and at least one inlet pipe lumen for connection to a fluid supply tube. Lockwood discloses a conformable wound dressing 20 made of medical grade silicone comprising a backing layer 62 capable of forming a fluid-tight seal over a wound and a wound-facing face 22 and at least one inlet lumen, namely vacuum/irrigation port 26 for connection to a fluid supply tube. Since Lockwood seeks to solve a similar problem in the art to that with which the applicant is concerned and the wound dressing disclosed by Lockwood provides passageways 28 that direct either vacuum flow or irrigation fluid (and thus also physiological agent) for even dispersion in the wound, one of ordinary skill in the art would be motivated to modify the apparatus disclosed by Swanbeck by adding the conformable wound dressing disclosed by Lockwood to provide a way of evenly distributing either suction flow or therapeutic fluid for more even and quicker healing of the wound.

With respect to **claim 2**: The examiner is invoking 35 U.S.C. 112, sixth paragraph in the interpretation of claim 2. The means for supplying physiologically active agents to the wound disclosed by Swanbeck comprises the fluid reservoir 15. With regard to the limitation "containing physiologically active components in therapeutically active amounts to promote wound healing", Swanbeck discloses physiologically active agents, e.g. vitamins and amino acids. (Page 4, ¶2) In light of the lack of clear definition in the applicant's specification or the original claims for the phrase "therapeutically active amounts to promote wound healing", the clinical tests cases and results disclosed by Swanbeck (see pages 6-8) that illustrate wound healing are evidence that Swanbeck fairly suggests physiologically active components in therapeutically active amounts to promote wound healing, rendering claim 2 unpatentable.

Art Unit: 3761

With respect to **claim 3**: Swanbeck discloses physiologically active agents, e.g. amino acids, i.e. materials to achieve the delivery of nucleic acid molecules as active genes. (Page 4, ¶2)

With respect to **claim 6**: Swanbeck discloses that the physiologically active agents for supply supplied to the wound are antibiotics. (Page 4, ¶2)

With respect to **claims 8,17**: The examiner is invoking 35 U.S.C. 112, sixth paragraph in the interpretation of claim 8. The means for fluid cleansing disclosed by Swanbeck comprises a two-phase system configured to remove materials deleterious to wound healing from fluid removed from the wound through lumen 12 by bringing fluid removed from the wound into direct or indirect contact with a second fluid in bottle 15. (Page 5, ¶1)

With respect to **claim 12**: Swanbeck discloses a method of treating wounds to promote wound healing using the apparatus for aspirating, irrigating and/or cleansing wounds according to all of the limitations of claim 1, except for a conformable wound dressing comprising a backing layer which is capable of forming a relatively fluid-tight seal or closure over a wound and a wound-facing face. Lockwood discloses a conformable wound dressing 20 made of medical grade silicone comprising a backing layer 62 capable of forming a fluid-tight seal over a wound and a wound-facing face 22 and at least one inlet lumen, namely vacuum/irrigation port 26 for connection to a fluid supply tube. Since Lockwood seeks to solve a similar problem in the art to that with which the applicant is concerned and the wound dressing disclosed by Lockwood provides passageways 28 that direct either vacuum flow or irrigation fluid (and thus also physiological agent) for even dispersion in the wound, one of ordinary skill in the art would be motivated to modify the apparatus and method disclosed by Swanbeck by adding the

conformable wound dressing disclosed by Lockwood to provide a way of evenly distributing either suction flow or therapeutic fluid for more even and quicker healing of the wound.

With respect to **claim 22**: The apparatus disclosed by Swanbeck further comprises a fluid cleansing mechanism, filter 14, in fluid communication with the outlet lumen 12, the fluid cleansing mechanism configured to remove materials deleterious to wound healing from fluid in the outlet lumen. (Page 3, ¶3)

6. Claims 4 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swanbeck ('904) in view of Lockwood ('681) as applied to claim 1 above, and further in view of Peshoff (U.S. Patent Application Publication No. 2002/0114847).

With respect to **claims 4,18**: Swanbeck discloses physiologically active agents, e.g. enzymes for digesting necrotic tissue, coagulum and pus, supplied to the wound that are materials that are beneficial in promoting wound healing by removing materials from a wound exudate or by regulating, limiting or inhibiting processes deleterious to wound healing from wound exudate. (Page 4, ¶2) Swanbeck does not disclose that the physiologically active agents are selected from the group consisting of natural purified protein: recombinant-produced protein proteinase inhibitors; inhibitors of inhibitors of angiogenesis; antioxidants; free radical scavengers; degraders; free radical generators; and a combination thereof. Peshoff discloses a wound-healing compound comprising antioxidants. Since the compound of Peshoff seeks to solve a similar problem in the art, one of ordinary skill in the art would be motivated to modify the apparatus disclosed by Swanbeck such that the solution is that disclosed by Peshoff to ensure effective wound healing. ('847, [0009])

7. Claims 5 and 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Swanbeck ('904) in view of Lockwood ('681) as applied to claim 1 above, and further in view of Boykin, Jr (U.S. Patent Application Publication No. 2003/0134332).

With respect to **claims 5,16**: Swanbeck discloses enzymes for digestion of necrotic tissue but does not disclose that the physiologically active agents supplied to the wound are recombinant-produced protein debriding agents. Boykin, Jr. discloses a composition for treating endothelial dysfunction and wounds by applying a therapeutic amount of platelet-derived growth factor (PDGF), which is identical to a recombinant-produced protein agent disclosed by the applicant and is fully capable of regulating cell growth and is fully capable of acting as a debriding agent. Since the solution disclosed by Boykin seeks to solve a similar problem in the art to that with which the applicant is concerned, one of ordinary skill in the art would be motivated to modify the apparatus disclosed by Swanbeck such that the active agent is PDGF as disclosed by Boykin to regulate skin cell growth and proliferation, thus facilitating wound healing and removal of necrotic tissue. ('128, [0069])

8. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Swanbeck ('904) in view of Lockwood ('681) as applied to claim 1 above, and further in view of Lina et al (6,695,823).

With respect to **claim 13**: The examiner is invoking 35 U.S.C. 112, sixth paragraph in the interpretation of claim 13. Swanbeck does not disclose any means for bleeding the fluid flowpath. Lina discloses a wound treatment apparatus comprising a bleed valve 86 for bleeding

the vacuum line to relieve accumulating pressure in the line. Thus one of ordinary skill in the art would be motivated to modify the apparatus disclosed by Swanbeck so as to provide a means for bleeding fluid from the recirculation lumen as disclosed by Lina to prevent complications from accumulated pressure in the line that could adversely effect the apparatus and the wound environment. ('823, Col. 12, lines 50-65)

9. Claims 19-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swanbeck ('904) in view of Lockwood ('681) as applied to claim 14 above, and further in view of Quirk et al (U.S. Patent Application Publication No. 2003/0148959).

With respect to **claims 19-21**: Swanbeck does not disclose that the irrigation fluid comprises an antibacterial derivative of acetic acid. Quirk discloses a wound healing composition comprising chlorhexidine acetate. As chlorhexidine acetate is an antibacterial agent, one of ordinary skill in the art would be motivated to modify the apparatus disclosed by Swanbeck such that the treating composition comprises chlorhexidine acetate as disclosed by Quirk. ('959, [0190])

Allowable Subject Matter

10. Claims 9, 10 and 23 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Reasons for Indicating Allowable Subject Matter

11. The following is a statement of reasons for the indication of allowable subject matter:
 - a. With respect to claims 9 and 10, the closest prior art of record, the combination of Swanbeck and Lockwood, does not meet the limitation of an apparatus wherein, in the means for fluid cleansing, the circulating fluid removed from the wound and the second fluid in the means for fluid cleansing are separated by an integer which is selectively (claim 9) or not selectively (claim 10) permeable to materials deleterious to wound healing. WO 2000/50143 A1 to Treu et al discloses a peritoneal dialysis circuit comprising a means for fluid cleansing wherein circulating fluid removed from the peritoneal cavity of a patient and a second fluid, regeneration solution, are separated by an integer 26 that is selectively or non-selectively permeable to materials deleterious to wound healing. However Treu does not disclose a wound dressing, comprising a backing layer forming a fluid-tight seal or closure and a wound-facing face. Thus combination of Treu with either of Swanbeck or Lockwood would not meet all of the limitations of claim 1 and claims 9 and 10 which depend from claim 1. Further, one of ordinary skill in the art would not be motivated to modify the Swanbeck apparatus to include an integer as taught by Treu because the permeability and diffusion of harmful materials out of the outgoing fluid in the circuit from the peritoneal cavity relies on dynamic fluid flow, which is not present in the Swanbeck apparatus and cannot be accomplished by any of the components of the Swanbeck device in combination with the present structure, i.e. attempt to have counterflow of two fluids in a bottle sufficient to effect diffusion as desired.
 - b. With respect to claim 23, Swanbeck does not disclose or suggest a fluid recirculation lumen for directing cleansed fluid from the means for fluid cleansing back

into the inlet lumen without passing through the fluid reservoir, as the reservoir is the means for fluid cleansing. Therefore Swanbeck teaches away from such a lumen.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELANIE HAND whose telephone number is (571)272-6464. The examiner can normally be reached on Mon-Thurs 8:00-5:30, alternate Fridays 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melanie J Hand/
Primary Examiner, Art Unit 3761